UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,302	07/18/2003	Karen Stec	ALS-2	7280

7590 12/28/2006

Jeffrey M. Hoster
13 Woodland Drive
Lemont, IL 60439

EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/28/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/622,302	STEC ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *9-14 and 24-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 15-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/8/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of ischemia/reperfusion as the dysfunction and alteplase as the therapeutic agent in the replies filed on 9/8/2006 and 11/7/2006 respectively is acknowledged. Claims 1-8 and 15-23 read on the elected species and are being examined on their merits herein. Claims 9-14 and 24-33 do not read on the elected species and are withdrawn from consideration. The election restriction requirement is deemed proper and made **FINAL**.

Claim Rejections – 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected,.to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 15-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating dysfunction, damage and/or injuries to organs, tissues, and/or cells comprising administration of 2,3-alkylcarbonyloxybenzoic acid, does not reasonably provide enablement for the prevention of dysfunction, damage and/or injuries to organs, tissues, and/or cells comprising administration of 2,3-alkylcarbonyloxybenzoic acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is

directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention: The rejected claims 1-8 and 15-23 are drawn to a method for preventing and/or treating dysfunction, damage and/or injuries to organs, tissues, and/or cells comprising administration of one or more compounds selected from the group consisting of 2,3-alkylcarbonyloxybenzoic acid.

(2) The state of the prior art: The state of the art regarding treating various types of dysfunctions, damage and/or injuries to organs, tissues, and/or cells is relatively high. However, the state of the art for prevention of dysfunctions, damage and/or injuries to organs, tissues, and/or cells is underdeveloped.

(3) The relative skill of those in the art: The relative skill of those in the art is high.

(4) The breadth of the claims: The claims 1-8 and 15-23 embrace preventing and/or treating dysfunction, damage and/or injuries to organs, tissues, and/or cells comprising administration of one or more compounds selected from the group consisting of 2,3-alkylcarbonyloxybenzoic acid.

(5) The amount of guidance or direction presented: In the instant case, no working examples are presented in the specification as filed showing how to prevent all dysfunction, damage and/or injuries to organs, tissues, and/or cells. Note that lack of a working example is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP § 2164. The specification on pages 10-11 details studies performed in guinea pig models of lung injury and sepsis in which 2,3-diacetoxybenzoic acid treatment was shown to improve lung injury and sepsis proving that 2,3-diacetoxybenzoic acid improves lung injury and sepsis but does not prevent either of these dysfunctions.

(6) The presence or absence of working examples: Applicant does not provide any working examples for the prevention of dysfunction, damage and/or injuries to organs, tissues, and/or cells.

(7) The quantitation of experimentation necessary: Claims 1-8 and 15-23 read on the prevention of dysfunction, damage and/or injuries to organs, tissues, and/or cells. As discussed above, the specification fails to provide sufficient support for completely protecting against dysfunction, damage and/or injuries to organs, tissues, and/or cells. Applicant fails to provide information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Claims 1-8 and 15-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating lung injury and sepsis with 2,3-diacetoxybenzoic acid, does not reasonably provide enablement for treating all dysfunctions, damage and/or injuries to organs, tissues, and/or cells with all 2,3-alkylcarbonyloxybenzoic acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention: The rejected claims 1-8 and 15-23 are drawn to a method for preventing and/or treating dysfunction, damage and/or injuries to organs, tissues, and/or cells comprising administration of one or more compounds selected from the group consisting of 2,3-alkylcarbonyloxybenzoic acid.

(2) The state of the prior art: The state of the art regarding treating various types of dysfunctions, damage and/or injuries to organs, tissues, and/or cells is relatively high. However, the state of the art for treating all dysfunctions, damage and/or injuries to organs, tissues, and/or cells with all types of 2,3-alkylcarbonyloxybenzoic acids is underdeveloped.

(3) The relative skill of those in the art: The relative skill of those in the art is high.

(4) The breadth of the claims: The claims 1-8 and 15-23 embrace preventing and/or treating dysfunction, damage and/or injuries to organs, tissues, and/or cells comprising administration of one or more compounds selected from the group consisting of 2,3-alkylcarbonyloxybenzoic acid.

(5) The amount of guidance or direction presented: In the instant case, no working examples are presented in the specification as filed showing how to treat all dysfunctions, damage and/or injuries to organs, tissues, and/or cells with all 2,3-alkylcarbonyloxybenzoic acids. Note that lack of a working example is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP § 2164. The specification on pages 10-11 details studies performed in guinea pig models of lung injury and sepsis in which 2,3-diacetoxybenzoic acid treatment was shown to improve lung injury and sepsis proving that 2,3-diacetoxybenzoic acid improves lung injury and sepsis; however, the specification does not provide examples for treating all dysfunctions, damage and/or injuries to organs, tissues, and/or cells with all 2,3-alkylcarbonyloxybenzoic acids.

(6) The presence or absence of working examples: Applicant does not provide any working examples for the treatment of dysfunctions, damage and/or injuries to organs, tissues and/or cells with all 2,3-alkylcarbonyloxybenzoic acids.

(7) The quantitation of experimentation necessary: Claims 1-8 and 15-23 read on the prevention of dysfunctions, damage and/or injuries to organs, tissues and/or cells comprising administration of compounds selected from the group of 2,3-alkylcarbonyloxybenzoic acids. As discussed above, the specification fails to provide sufficient support for treating all dysfunctions, damage and/or injuries to organs, tissues and/or cells comprising administration of all 2,3-alkylcarbonyloxybenzoic acids. Applicant fails to provide information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Claims 1-8 and 18-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of lung injury and sepsis with 2,3-diacetoxybenzoic acid, does not reasonably provide enablement for the treatment of the elected species ischemia/reperfusion with 2,3-diacetoxybenzoic acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention: The rejected claims 1-8 and 15-23 are drawn to a method for preventing and/or treating dysfunction, damage and/or injuries to organs, tissues, and/or cells, specifically the elected species ischemia/reperfusion, comprising administration of one or more compounds selected from the group consisting of 2,3-alkylcarbonyloxybenzoic acid.

(2) The relative skill of those in the art: The relative skill of those in the art is high.

(3) The breadth of the claims: The claims 1-8 and 15-23 embrace preventing and/or treating dysfunction, damage and/or injuries to organs, tissues, and/or cells, specifically the elected species ischemia/reperfusion, comprising administration of one or more compounds selected from the group consisting of 2,3-alkylcarbonyloxybenzoic acid.

(4) The amount of guidance or direction presented: In the instant case, no working examples are presented in the specification as filed showing how to treat ischemia/reperfusion with all 2,3-alkycarbonyloxybenzoic acids. Note that lack of a working example is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP § 2164. The specification on pages 10-11 details studies performed in guinea pig models of lung injury and sepsis in which 2,3-diacetoxybenzoic acid treatment was shown to improve lung injury and sepsis proving that 2,3-diacetoxybenzoic acid improves lung injury and sepsis; however, the specification does not provide examples for treating ischemia/reperfusion with 2,3-alkylcarbonyloxybenzoic acids.

(6) The presence or absence of working examples: Applicant does not provide any working examples for the treatment of ischemia/reperfusion with 2,3-alkylcarbonyloxybenzoic acids.

(7) The quantitation of experimentation necessary: Claims 1-8 and 15-23 read on the prevention of dysfunctions, damage and/or injuries to organs, tissues and/or cells, specifically the elected species ischemia/reperfusion, comprising administration of compounds selected from the group of 2,3-alkylcarbonyloxybenzoic acids. As discussed above, the specification fails to provide sufficient support for treating ischemia/reperfusion comprising administration of all 2,3-alkylcarbonyloxybenzoic acids. Applicant fails to provide information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful

conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-23 provides for the use of an effective therapeutic amount of one or more compounds selected from the group consisting of 2,3-alkylcarbonyloxybenzoic acids in the treatment of one or more diseases or conditions, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. For compact prosecution, it is interpreted that claims 18-23 are referring to a method of treating one or more diseases with one or more compounds selected from the group consisting of 2,3-alkylcarbonyloxybenzoic acids.

Claim Rejections – 35 USC § 101

Claims 18-23 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Conclusion

Claims 1-8 and 15-23 are free of the art.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER